IN THE CLAIMS:

Please cancel claims 1-81 and insert the following new claims therefor:

82. A method of screening a sample of body fluid for at least one autoantibody to at least one antigen, which method comprises:

(a) providing a source of said at least one antigen to said autoantibody;

(b) providing a substrate having immobilized thereto at least one antibody to said antigen of step (a);

(c) contacting said antigen source of step (a) with said sample of body fluid, so as to obtain a mixture wherein said antigen is allowed to substantially bind with said autoantibody, when the latter is present in said sample;

(d) allowing said mixture obtained in step (c) to flow relative to said substrate of step (b) so as to allow said mixture to contact said antibody immobilized to said substrate;

(e) providing labelling means so as to permit monitoring of binding of said autoantibody and said antigen present in said mixture obtained in step (c); and

(f) monitoring said binding so as to provide an indication of the presence of said autoantibody in said sample of body fluid.

83. A method according to claim 82, wherein said antigen comprises a thyroid protein.

84. A method according to claim 83, wherein said thyroid protein includes thyroid stimulating hormone receptor.

85. A method according to claim 83, wherein said thyroid protein is selected from the group consisting of thyroid peroxidase and thyroglobulin.

86. A method according to claim 82, which further comprises screening for the presence of at least one of thyroid stimulating hormone, thyroxine, tri-iodothyronine and thyroglobulin in said sample of body fluid.

87. A method according to claim 82, which comprises contacting in step (c) said antigen source and said sample of body fluid with at least one substantially non-immobilized antibody to said antigen.

88. A method according to claim 87, wherein said non-immobilized antibody is provided in substantially purified form.

89. A method according to claim 87, wherein said non-immobilized antibody is selected from the group consisting of a monoclonal antibody and an autoantibody to said antigen.

90. A method according to claim 82, wherein said monitoring in step (f) comprises observing a colorimetric change dependent on said binding of said autoantibody and said antigen present in said mixture of step (c).

91. A method according to claim 90, wherein said labelling means include colloidal gold.

92. A method according to claim 82, which further comprises providing a positive control that is present in the presence or absence of the autoantibody or autoantibodies being screened.

93. A method according to claim 82, wherein said mixture obtained in step (c) is allowed to flow along said substrate and interact with said antibody immobilized to said substrate.

94. A method according to claim 93, wherein at least said sample of body fluid is contacted with an application zone of said substrate, which

application zone is provided upstream on said substrate relative to said immobilized antibody, and wherein said mixture is allowed to flow from said application zone along said substrate so as to interact with said immobilized antibody.

95. A method according to claim 94, wherein said application zone includes said source of said antigen of step (a), and said mixture in step (c) is obtained by contacting said sample of body fluid with said antigen of said application zone.

96. A method according to claim 94, wherein said application zone further includes at least one substantially non-immobilized antibody to said antigen, and said mixture in step (c) is obtained by contacting said sample of body fluid and said antigen with said non-immobilized antibody present in said application zone.

97. A method according to claim 94, wherein said antigen source of step (a) and said sample of body fluid are contacted substantially remote from said substrate so as to provide said mixture of step (c), and said mixture is subsequently contacted with said application zone.

98. A method according to claim 97, wherein at least one reagent selected from said antigen source of step (a), said sample of body fluid and at least one substantially non-immobilized antibody to said antigen, is contacted substantially remote from said substrate so as to provide said mixture of step (c), and said mixture is subsequently contacted with said application zone.

99. A method according to claim 82, wherein said substrate is a membrane selected from the group consisting of nitrocellulose, cellulose acetate and polyamide.

100. A method according to claim 82, wherein said immobilized antibody is in substantially purified form.

101. A method according to claim 82, wherein said immobilized antibody is selected from the group consisting of an autoantibody to said antigen and a monoclonal antibody.

102. A method according to claim 82, wherein said sample of body fluid is selected from the group consisting of blood, plasma, serum and urine.

103. A method according to claim 82, which comprises screening said sample of body fluid for one said autoantibody.

104. A method according to claim 103, wherein said antigen includes a binding site to which either said autoantibody or said immobilized antibody can bind, whereby in step (d) binding of said immobilized antibody to said binding site is substantially precluded where said autoantibody has substantially bound to said binding site in step (c).

105. A method according to claim 82, which comprises screening said sample of body fluid for at least first and second autoantibodies to said antigen, wherein at least first and second antibodies to said antigen are immobilized on said substrate in step (b).

106. A method according to claim 105, wherein said antigen includes:

a first binding site to which either said first autoantibody or said first immobilized antibody can bind, whereby in step (d) binding of said first immobilized antibody to said first binding site is substantially precluded where said first autoantibody has substantially bound to said first binding site in step (c); and

a second binding site to which either said second autoantibody or said second immobilized antibody can bind, whereby in step (d) binding of said second immobilized antibody to said second binding site is substantially precluded where said second autoantibody has substantially bound to said second binding site in step (c);

wherein said first and second binding sites are substantially distinct sites on said antigen.

107. A method according to claim 82, wherein said antigen is provided with said labelling means.

108. A method according to claim 92, wherein said positive control comprises attaching to the substrate at least one control antibody to the antigen, which control antibody binds to a site on the antigen distinct to a binding site thereof for the autoantibody or autoantibodies being screened.

109. A method according to claim 87, wherein said non-immobilized antibody is provided with said labelling means, which non-immobilized antibody is capable of binding to a site on said antigen substantially distinct from a binding site for either (i) said autoantibody or autoantibodies being screened or (ii) said immobilized antibody, whereby in step (d), antigen is allowed to be substantially bound both to said immobilized antibody and to said non-immobilized antibody.

110. A method according to claim 87, which comprises screening said sample of body fluid for at least first and second autoantibodies to said antigen, wherein said non-immobilized antibody is capable of binding to a site on said antigen to which either said first or second autoantibody can bind and which is substantially distinct to a binding site on said antigen for said immobilized antibody, whereby in step (d) antigen is allowed to be substantially bound both to said immobilized antibody and to said non-immobilized antibody.

111. A method according to claim 110, wherein said antigen includes:

a first binding site to which either said first autoantibody or said immobilized antibody can bind, whereby in step (d) binding of immobilized antibody to said first binding site is substantially precluded where said first autoantibody has substantially bound to said first binding site in step (c); and

a second binding site to which either said second autoantibody or said non-immobilized antibody can bind;

wherein said first and second binding sites are substantially distinct sites on said antigen.

112. A method according to claim 110, wherein said non-immobilized antibody is provided with said labelling means.

113. A method according to claim 110, wherein said immobilized antibody comprises a first autoantibody to said antigen and said non-immobilized antibody comprises a second autoantibody to said antigen.

114. A method according to claim 87 which further comprises a positive control that is present in the presence or absence of the autoantibody or autoantibodies being screened, wherein the positive control comprises attaching to the substrate at least one control agent that can bind to the at least one substantially non-immobilized antibody.

115. A kit for use in screening a sample of body fluid for at least one autoantibody to at least one antigen, which kit comprises:

(a) a source of said at least one antigen to said autoantibody;

(b) a substrate having immobilized thereto at least one antibody to said antigen;

(c) means for contacting said antigen source with said sample of body fluid, so as to obtain a mixture wherein said antigen is

allowed to substantially bind with said autoantibody, when the latter is present in said sample;

(d) means for allowing said mixture to flow relative to said substrate so as to allow said mixture to contact said antibody immobilized to said substrate;

(e) labelling means to permit monitoring of binding of said autoantibody and said antigen present in said mixture; and

(f) means for monitoring said binding so as to provide an indication of the presence of said autoantibody in said sample of body fluid.

116. A kit according to claim 115, wherein said antigen comprises a thyroid protein.

117. A kit according to claim 116, wherein said thyroid protein includes thyroid stimulating hormone receptor.

118. A kit according to claim 116, wherein said thyroid protein is selected from the group consisting of thyroid peroxidase and thyroglobulin.

119. A kit according to claim 115, which further comprises means for screening for the presence of at least one of thyroid stimulating hormone, thyroxine, tri-iodothyronine and thyroglobulin in said sample of body fluid.

120. A kit according to claim 115, which further comprises a source of at least one substantially non-immobilized antibody to said antigen and means whereby said non-immobilized antibody can be contacted with said antigen source and said sample of body fluid.

121. A kit according to claim 120, wherein said non-immobilized antibody is provided in substantially purified form.

122. A kit according to claim 120, wherein said non-immobilized antibody is selected from the group consisting of a monoclonal antibody and an autoantibody to said antigen.

123. A kit according to claim 115, wherein said monitoring means comprise means for observing a colorimetric change dependent on said binding of said autoantibody and said antigen present in said mixture.

124. A kit according to claim 123, wherein said labelling means include colloidal gold.

125. A kit according to claim 115, which further comprises a positive control that is present in the presence or absence of the autoantibody being screened.

126. A kit according to claim 115, wherein said substrate comprises an application zone for at least said sample of body fluid, which application zone is provided upstream on said substrate relative to said immobilized antibody, whereby said mixture is allowed to flow from said application zone along said substrate so as to interact with said immobilized antibody.

127. A kit according to claim 126, wherein said application zone includes said source of said antigen, and said mixture is obtained by contacting said sample of body fluid with said antigen of said application zone.

128. A kit according to claim 126, wherein said application zone further includes at least one substantially non-immobilized antibody to said antigen, and means whereby said mixture is obtained by contacting said sample of body fluid and said antigen with said non-immobilized antibody present in said application zone.

129. A kit according to claim 126, wherein means are provided whereby said antigen source and said sample of body fluid are contacted substantially remote from said substrate so as to provide said mixture and means whereby said mixture is subsequently contacted with said application zone.

130. A kit according to claim 129, wherein means are provided whereby at least one reagent selected from said antigen source, said sample of body fluid and at least one substantially non-immobilized antibody to said antigen, is contacted substantially remote from said substrate so as to provide said mixture, and means whereby said mixture is subsequently contacted with said application zone.

131. A kit according to claim 115, wherein said substrate is a membrane selected from the group consisting of nitrocellulose, cellulose acetate and polyamide.

Ins B,7

132. A kit according to claim 115, wherein said immobilized antibody is provided in substantially purified form.

133. A kit according to claim 115, wherein said immobilized antibody is selected from the group consisting of an autoantibody to said antigen and a monoclonal antibody.

134. A kit according to claim 115, wherein said sample of body fluid is selected from the group consisting of blood, plasma, serum and urine.

Ins B,8

135. A kit according to claim 115, for screening said sample of body fluid for one said autoantibody, wherein said antigen includes a binding site to which either said autoantibody or said immobilized antibody can bind, whereby binding of said immobilized antibody to said binding site is

substantially precluded where said autoantibody has previously substantially bound to said binding site.

136. A kit according to claim 115, for screening said sample of body fluid for at least first and second autoantibodies to said antigen, wherein at least first and second antibodies to said antigen are immobilized on said substrate.

137. A kit according to claim 136, wherein said antigen includes:

a first binding site to which either said first autoantibody or said first immobilized antibody can bind, whereby binding of said first immobilized antibody to said first binding site is substantially precluded where said first autoantibody has previously substantially bound to said first binding site; an

a second binding site to which either said second autoantibody or said second immobilized antibody can bind, whereby binding of said second immobilized antibody to said second binding site is substantially precluded where said second autoantibody has previously substantially bound to said second binding site;

wherein said first and second binding sites are substantially distinct sites on the antigen.

138. A kit according to claim 115, wherein said antigen is provided with said labelling means.

139. A kit according to claim 125, wherein the positive control comprises attaching to the substrate at least one control antibody to the antigen, which control antibody binds to a site on the antigen distinct to a binding site thereof for the autoantibody or autoantibodies being screened.

140. A kit according to claim 120, wherein said non-immobilized antibody is provided with said labelling means, which non-immobilized antibody is capable of binding to a site on said antigen substantially distinct

from a binding site for either (i) said autoantibody or autoantibodies being screened or (ii) said immobilized antibody, whereby antigen is allowed to be substantially bound both to said immobilized antibody and to said non-immobilized antibody.

141. A kit according to claim 120 for screening said sample of body fluid for at least first and second autoantibodies to said antigen, wherein said non-immobilized antibody is capable of binding to a site on said antigen to which either said first or second autoantibody can bind and which is substantially distinct to a binding site on said antigen for said immobilized antibody, whereby antigen can be substantially bound both to said immobilized antibody and to said non-immobilized antibody.

142. A kit according to claim 141, wherein said antigen includes:

a first binding site to which either said first autoantibody or said immobilized antibody can bind, whereby binding of immobilized antibody to said first binding site is substantially precluded where said first autoantibody has previously substantially bound to said first binding site; and

a second binding site to which either said second autoantibody or said non-immobilized antibody can bind;

wherein said first and second binding sites are substantially distinct sites on said antigen.

143. A kit according to claim 141, wherein said non-immobilized antibody is provided with said labelling means.

144. A kit according to claim 141, wherein said immobilized antibody comprises a first autoantibody to said antigen and said non-immobilized antibody comprises a second autoantibody to said antigen.

145. A kit according to claim 120 which further comprises a positive control that is present in the presence or absence of the at least one

autoantibody being screened, wherein the positive control comprises at least one control agent attached to the substrate that can bind to the at least one substantially non-immobilized antibody.

146. A method of screening a patient for at least one autoantibody to at least one antigen, which method comprises:

(a) obtaining a sample of body fluid from said patient;

(b) contacting said sample of body fluid of step (a) with an antigen source of a kit according to claim 115, so as to obtain a mixture wherein said antigen is allowed to substantially bind with said autoantibody, when the latter is present in said sample;

(c) allowing said mixture to flow relative to a substrate of said kit so as to allow said mixture to contact said antibody immobilized to said substrate; and

(d) monitoring binding of said autoantibody and said antigen present in said mixture, so as to provide an indication of the presence of said autoantibody in said sample of body fluid from said patient.

147. A method according to claim 146, for testing said patient for an autoimmune thyroid disease.

148. A method according to claim 146, which further comprises screening for the presence of at least one of thyroid stimulating hormone, thyroxine, tri-iodothyronine and thyroglobulin in said sample of body fluid.

149. A method of treating a patient suffering from, or susceptible to, an autoimmune disease, which method comprises:

screening said patient for at least one autoantibody to at least one antigen as defined in claim 146; and

when at least one autoantibody is detected in a sample of body fluid obtained from said patient at a level indicative of an autoimmune disease,